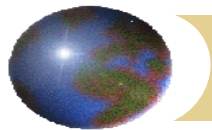


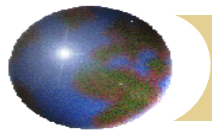
US FDA Medical Device Premarket Procedures

*Presenter: Timothy A. Ulatowski
VP, NSF Health Sciences*



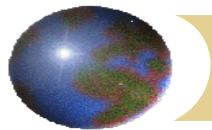
Overview

- ✚ Introductory Remarks
- ✚ Background on FDA medical device premarket organization
- ✚ A few basics of FDA medical device laws pertaining to premarket procedures
- ✚ Some background on pathways to placing a device on the market in the US



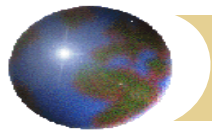
Overview Continued

- ✚ Premarket approval
- ✚ Premarket notification
- ✚ Available FDA reference material
- ✚ Questions



Introductory Remarks

- ✚ Listening to presentations on laws and regulations is not one of the most stimulating things we do in life
- ✚ This is a highly condensed discussion of very detailed technical topics that are not static
- ✚ There are more commonalities and fewer differences globally; CTD, IMDRF



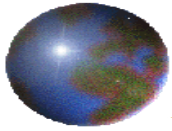
Introductory Remarks

- ✚ I hope at the end of today you have a basic understanding of FDA's premarket processes; not mastery
- ✚ Through international collaboration on premarket topics we help ensure global safety and effectiveness of medical devices



U.S. Department of Health and Human Services
Food and Drug Administration

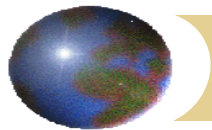




FDA

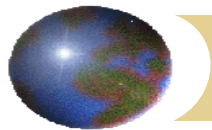


*ITA-FDA Medical Devices Regulatory Capacity Building Training Program for International Medical Devices Regulators
March 27 - 28, 2014; San Francisco, California*



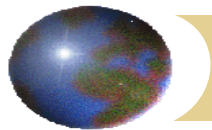
FDA Premarket Organization

- ✚ Federal regulation of devices is centralized in the FDA; FDA is the competent authority
- ✚ FDA consists of product centers; one is Center for Devices and Radiological Health (CDRH)
- ✚ CDRH consists of 7 offices; 7 have premarket activities:



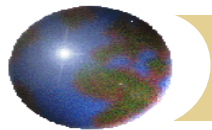
FDA Premarket Organization

- ✚ Device Evaluation*
- ✚ In Vitro Diagnostics and Radiological Health*
- ✚ Surveillance and Biometrics - assists
- ✚ Science and Engineering Labs - assists
- ✚ Compliance – assists
- ✚ Management Operations – supportive
- ✚ Communication, Education - supportive



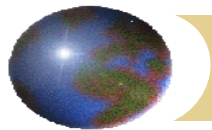
FDA Premarket Organization

- ✚ ODE and OIVD divided into divisions, divisions divided into branches; branches are the interface with manufacturers and where review staff reside
- ✚ FDA relies on its own staff, external experts, fellows, third parties, and others to assist with premarket review



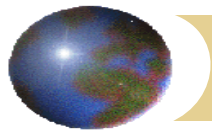
Basics of Relevant Law

- ✚ Federal Food, Drug and Cosmetic Act; 1976 and other device amendments
- ✚ Prohibited Acts (some) – You cannot...
 - ▣ Put a device in commerce that does not have premarket approval or premarket notification, if required
 - ▣ You must comply with quality system requirements



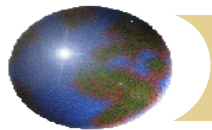
Basics of Relevant Law

- ✚ Establishment of three Classes of devices; fundamental to premarket processes
 - ▣ Class I – subject to general controls
 - ▣ Class II – general and special controls
 - ▣ Class III – general controls and premarket approval



Basics of Relevant Law

- ✚ Meeting requirements of the class provides reasonable assurance of safety and effectiveness

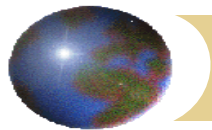


Basics of Relevant Law

✚ General Controls (not all listed)

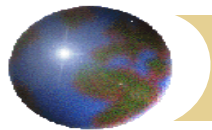
- ✚ Registration/listing
- ✚ Quality systems
- ✚ Adulteration and misbranding
- ✚ Reports (MDRs, corrections and removals)

✚ Special controls – as FDA determines and made part of device type class regulation



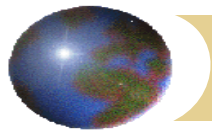
Basics of Relevant Law

- ✚ Classification of device types on market **before 1976** is based on rules.
 - ▣ Class I – general controls sufficient or not a risk
 - ▣ Class II – general controls alone insufficient and there is information to establish special controls
 - ▣ Class III – General controls insufficient, cannot make and special control and high degree of risk
- ✚ See 21 CFR 800 series for classifications



Basics of Relevant Law

- ✚ Classification of **post 1976** devices:
 - ✚ Class III unless
 - ✚ “Substantially equivalent” to pre 1976 device or to a post 1976 device that does not require premarket approval
- ✚ Reclassification process (topic for another day)



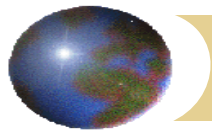
Basics of Relevant Regulation

✚ Important classification definitions:

- ▣ "Valid scientific evidence"

- ▣ "safe"

- ▣ "effective"

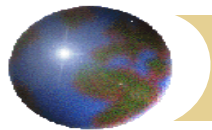


Basics of Relevant Regulation

✚ "Valid scientific evidence"

- ✚ Well controlled, partially controlled, no matched control
- ✚ Well documented case histories
- ✚ Significant experience

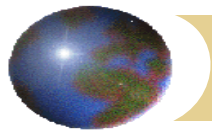
✚ Not valid evidence – isolated cases, random experience



Basics of Relevant Regulation


"Safe"

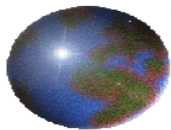
- Based on valid scientific evidence the probable benefits when used according to labeling outweigh any probable risks
- Absence of unreasonable risk



Basics of Relevant Regulation

"Effective"

-  Based on valid scientific evidence in a significant portion of the target population when the device is used according to labeling the device will provide clinically significant results



Determining Class



U.S. Food and Drug Administration
Protecting and Promoting *Your Health*

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[Radiation-Emitting Products](#)

[Vaccines, Blood & Biologics](#)

[Animal & Veterinary](#)

[Cosmetics](#)

[Tobacco Products](#)



For Consumers & Patients

Updates and information for staying safe and healthy



For Health Professionals

Medical product safety information, adverse event/problem reporting and more



For Scientists & Researchers

NCTR, pediatrics, clinical trials, Critical Path Initiative and more



For Industry

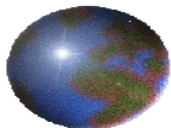
Guidance, registration and listing, import programs and more

[Recalls & Alerts](#)

[Approvals & Clearances](#)

[Report a Problem](#)

MARCH 27 - 28, 2014; SAN FRANCISCO, CALIFORNIA



Determining Class

Product Classification

◀ FDA Home ▶ Medical Devices ▶ Databases



This database includes:

- a list of all medical devices with their associated classifications, product codes, FDA premarket review organizations, and other regulatory information.

[Learn More...](#)

Search Database



Help



Download Files

Device

Product Code

Review Panel

Regulation Number

SubmissionType

Third Party Eligible

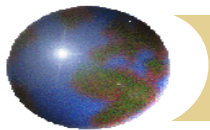
Device Class

[Go to Quick Search](#)

[Clear Form](#)

Other Databases

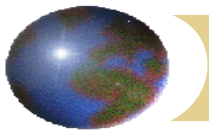
- 510(k)s
- Adverse Events (MAUDE)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- Inspections
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Registration & Listing
- Standards
- Total Product Life Cycle
- X-Ray Assembler



Determining Class

Subpart C--General Hospital and Personal Use Monitoring Devices

- § 880.2200 - Liquid crystal forehead temperature strip.
- § 880.2400 - Bed-patient monitor.
- § 880.2420 - Electronic monitor for gravity flow infusion systems.
- § 880.2460 - Electrically powered spinal fluid pressure monitor.
- § 880.2500 - Spinal fluid manometer.
- § 880.2700 - Stand-on patient scale.
- § 880.2720 - Patient scale.
- § 880.2740 - Surgical sponge scale.
- § 880.2800 - Sterilization process indicator.
- § 880.2900 - Clinical color change thermometer.
- § 880.2910 - Clinical electronic thermometer.
- § 880.2920 - Clinical mercury thermometer.
- § 880.2930 - Apgar timer.



Determining Class

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

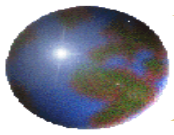
PART 880 -- GENERAL HOSPITAL AND PERSONAL USE DEVICES

Subpart C--General Hospital and Personal Use Monitoring Devices

Sec. 880.2500 Spinal fluid manometer.

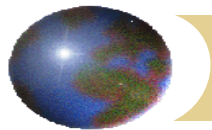
(a) *Identification.* A spinal fluid manometer is a device used to measure spinal fluid pressure. The device uses a hollow needle, which is inserted into the spinal column fluid space, to connect the spinal fluid to a graduated column so that the pressure can be measured by reading the height of the fluid.

(b) *Classification.* Class II (performance standards).



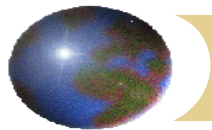
Pathways to the Market





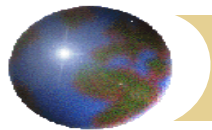
Pathways to the Market

- ✚ Foundation for safety and effectiveness and source of marketing submission, if needed, is the **technical file** - created, maintained and updated by the manufacturer
- ✚ Quality system regulation (and standard) and risk management standard: design, testing, production and postmarket processes



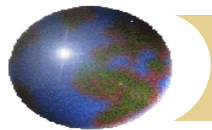
Pathways - Before Submission

- ✚ Clinical information may be needed for validation purposes and perhaps submission to FDA
- ✚ Sources:
 - ▣ Literature
 - ▣ Clinical experience – registries, MDRs...
 - ▣ Clinical investigation – IDE study



Pathways – Before Submission

- ✚ Requirements for shipment of devices to conduct investigational studies contained in IDE regulation, 21 CFR Part 812.
- ✚ Foreign studies not involving shipment from US not subject to FDA jurisdiction
- ✚ Human subject protections vital



Pathways – Three Paths

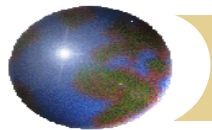
- ✚ **No submission** – “exempt devices” –

Class I (93%), several Class II (8%)

- ✚ Premarket notification [**510(k)**] – devices not exempt, not requiring premarket approval

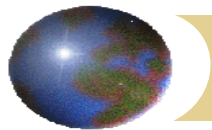
7% Class I, 92% Class II, (very few Class III*)

- ✚ Premarket approval (**PMA**) – Class III



Pathways – Exemption Void

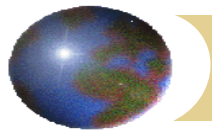
- ❖ Exemption no longer applies when new device compared to the generic devices in the exempt class: has new intended use or different fundamental technology, IVD with certain claims (21 CFR §§862.9, 864.9), or as specified in classification regulation



Pathways – Also No Submission

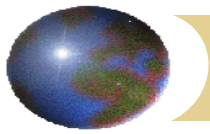
✚ Exempt devices:

- ✚ Unfinished devices, devices not sold in US, custom devices, veterinary devices, private label devices covered by another 510(k), pre-1976 devices still on the market



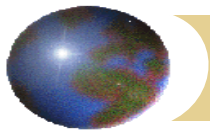
Premarket Approval Path (PMA)

- ❖ **Class III** device by classification regulation or a “not substantially equivalent” device as determined as a result of a 510(k) submission
- ❖ PMA regulation is 21 CFR Part 814
- ❖ Submission similarities in other countries (IMDRF)



PMA Process

- ✚ How does manufacturer know what to submit to FDA in a PMA?
 - ▣ Technical file is guided by QS regulation, prior PMA submissions, FDA guidance, standards, and IDE process
 - ▣ FDA provides input in Pre-IDE meeting, pre-PMA meeting

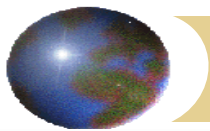


PMA Process – What to Submit

Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff

Guidance for Industry and Food and Drug Administration Staff

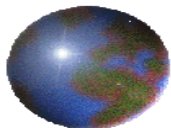
Document issued on: February 18, 2014



PMA Process – What to Submit

Q-Submission Types

Q-Submission Type	Meeting	Timeframe for Meeting/Teleconference (from receipt of submission)
Pre-Submission*	Upon request	75-90 days**
Informational Meeting	Yes	90 days
Study Risk Determination	No	N/A
Agreement Meeting	Yes	30 days or within time frame agreed to with sponsor
Determination Meeting	Yes	Date for meeting agreed upon within 30 days of request
Submission Issue Meeting	Yes	21 days
PMA Day 100 Meeting	Yes	100 days (from filing of PMA)



PMA Process - Guidance

Device Advice: Comprehensive Regulatory Assistance

► Guidance Documents (Medical Devices and Radiation-Emitting Products)

[Cross-Center Guidance Documents](#)

[OC Guidance](#)

[OCD Guidance](#)

[OCER Guidance](#)

[ODE Guidance 2010 - 2014](#)

[ODE Guidance 1998 - 2009](#)

[ODE Guidance 1976 - 1997](#)

[OIR Guidance](#)

[OSB Guidance](#)

[OSEL Guidance](#)

[Radiation-Emitting Products Guidance](#)

Guidance Documents (Medical Devices and Radiation-Emitting Products)

Search the Guidance Documents Section

SEARCH

[CDRH Industry: Get e-mail updates](#) 

We have recently redesigned the FDA Web site. As a result, some Web links (URLs) embedded within guidance documents are no longer valid. If you find a link that does not work, please try searching for the document using the document title.

About Guidance

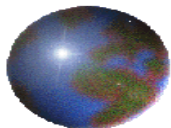
- [What is guidance?](#)
- [Abbreviations of CDRH offices producing guidance documents](#)

Resources

- [Guidance documents from FDA](#)
- [CDRH Fiscal Year 2014 \(FY 2014\) Proposed Guidance Development](#)

Additional Information

- [Blue Book Memos - ODE Guidance Memoranda](#)
- [Recent Medical Device Guidance Documents](#)
- [Most Popular Medical Device Guidance Documents](#)



PMA Process- Standards

Search Database



Standards Organization

All Standards Organizations

Standard Designation Number

Note: numbers only, e.g., 14971, 60601-1

Standards Title or Keywords

Note: do not include standard designation number

Specialty Task Group Area

All Categories

[Product Classification](#) Product Code

e.g., for vertical standard searches

Type of Standard

(use ctrl button with mouse click to select up to 3 types, e.g., Horizontal, National, Materials Specification)



All Standard Types

Vertical

Test Methods

National

[FR List Publication Date](#)

 to 

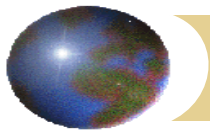
Sort By

Product Area, Item #

[Quick Search](#)

[Clear Form](#)

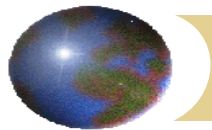
[Search](#)



PMA Process – PMA Submission

✚ Contents of a PMA, 21 CFR §814.20

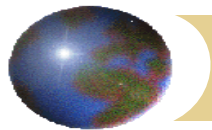
- ✚ Administrative information
- ✚ Summary: indications, description, alternatives, marketing history, summary/conclusions of studies
- ✚ Complete description: device, properties, principles of operation, manufacturing
- ✚ Standards used



PMA Process – PMA Submission

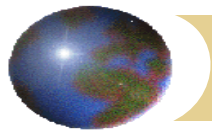
✚ Contents continued

- ✚ Technical sections: preclinical, engineering, clinical
- ✚ Bibliography
- ✚ Labeling
- ✚ Financial certification, environmental assessment



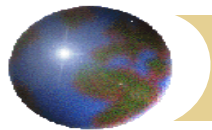
PMA Process – PMA Submission

- ✚ Two types of PMAs: traditional or modular
- ✚ Filing review by FDA
- ✚ Preapproval facility/BIMO inspection often required
- ✚ FDA review may result in questions
- ✚ FDA substantive review is followed by expert panel evaluation and recommendations



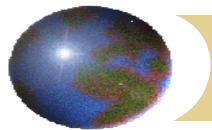
PMA Process – PMA Submission

- ✚ FDA Actions on a PMA, 180 day review cycle resulting in
 - ❏ Approved
 - ❏ Approvable – substantially meets requirements
 - ❏ Not approved – major deficiencies and measures to place in approvable form
 - ❏ Denial of approval – major deficiencies of a type that may not be correctable



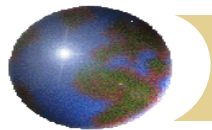
PMA Process – PMA Submission

- ✚ FDA may withdraw or suspend approval of a device
- ✚ Approval order contains any requirements pertaining to device such as annual reports, postmarket studies, specific labeling requirements



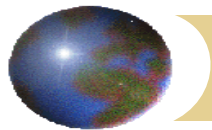
PMA Process- Supplements

- ✚ PMA supplements are required for changes affecting safety and effectiveness such as new indications, certain labeling changes, new facilities, certain change in performance, specs, sterilization, packaging...



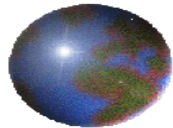
PMA Process- Supplements

- ❖ Changes not affecting safety and effectiveness are reported in annual report or 30 day notice
- ❖ labeling and manufacturing changes enhancing safety are submitted as supplements but may be initiated immediately.



PMA Process- Supplements

- ✚ Manufacturing Changes affecting safety and effectiveness submit as 30 day notices/135 day supplements
- ✚ FDA guidance on supplements, 30 day notices, preapproval inspections
- ✚ “Amendments” are submissions to PMAs or supplements prior to final decision

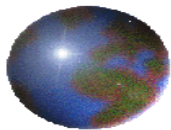


PMA Processes

- Other Class III processes will not be addressed in this training because of their limited use:

Product development protocol (PDP)

Humanitarian Use Device (HDE)

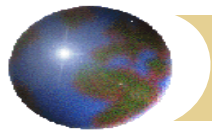


PMA Process

PMA Special Considerations

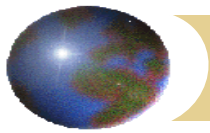
Please note: As of October 1, 2002, FDA charges

- Biocompatibility
- Color Additives
- Combination Products
- Electromagnetic Compatibility
- Electronic Submissions
- Environmental Impact Considerations
- Expedited Review
- Expiration Dating
- In Vitro Diagnostic (IVD) Products
- Master Files
- Radiation Emitting Products
- Software
- Standards
- Sterility



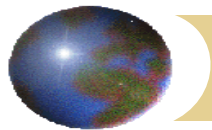
PMA Process

- ✚ Imported Class III device must be PMA approved
- ✚ Export of PMA approved devices – CFGs
- ✚ Export of unapproved Class III devices
 - ▣ Two methods – details in 802 and 801(e)(2) of the law



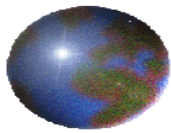
PMA Guidance

- **Guidance for Industry and FDA Staff - 30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes**
- **Acceptance of Foreign Clinical Studies**
- **Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products**
- **Balloon Valvuloplasty Guidance For The Submission Of an IDE Application and a PMA Application (Text Only)**
- **Bioresearch Monitoring Agreement for PMAs and PDPs - February 23, 1998**
- **Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Bone Sonometers**
- **Color Additive Petitions (PDF Only) (PDF - 91KB)**
- **Continued Access to Investigational Devices During PMA Preparation and Review July 15, 1996 (Blue Book Memo) (D96-1) (Text Only)**



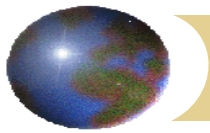
PMA Guidance

- **Distribution and Public Availability of Premarket Approval Application Summary of Safety and Effectiveness Data Packages - October 10, 1997 (P97-1) (Text Only)**
- **Early Collaboration Meetings Under the FDA Modernization Act (FDAMA); Final Guidance for Industry and for CDRH Staff**
- **Guidance for Industry and Food and Drug Administration Staff - Priority Review of Premarket Submissions for Devices**
- **Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals**
- **Guidance Document for the Preparation of IDE and PMA Applications for Intra-Articular Prosthetic Knee Ligament Devices**
- **Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests**
- **Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission**
- **Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies - for Use by CDRH and Industry**



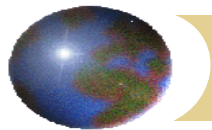
PMA Guidance

- **Guidance for Industry and for FDA Reviewers: Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997**
- **Guidance for Industry - Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review (Text Only)**
- **Panel Report and Recommendations on PMA Approvals #P86-5 (blue book memo) (Text Only)**
- **Panel Review of Premarket Approval Applications #P91-2 (blue book memo) (Text Only)**
- **PMA Compliance Program #P91-3 (blue book memo) (Text Only)**
- **Post Approval Studies Status**
- **PMA Review Statistical Checklist (PDF Only) (PDF - 69KB)**
- **Guidance for Industry and Food and Drug Administration Staff - Acceptance and Filing Reviews for Premarket Approval Applications (PMAs) (PDF - 370KB)**



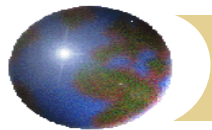
PMA Guidance

- **Premarket Approval Application Modular Review**
- **Premarket Approval Applications (PMA) for Sharps Needle Destruction Devices; Final Guidance for Industry and FDA**
- **Premarket Assessment of Pediatric Medical Devices**
- **Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff**
- **Real-Time Premarket Approval Application (PMA) Supplements**
- **The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry**
- **Threshold Assessment of the Impact of Requirements for Submission of PMAs for 31 Medical Devices Marketed Prior to May 28, 1976 (PDF Only) (PDF - 546KB)**
- **Guidance for Industry and Food and Drug Administration Staff - User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications**



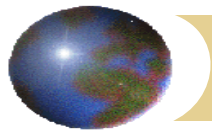
510(k) Path - What is a 510(k)

- ✚ Premarket Notification
- ✚ Section 510(k) of FDA law
- ✚ See 21 CFR Part 807, Subpart E
- ✚ Marketing clearance application
- ✚ Based on “substantial equivalence” to legally marketed device for which a PMA is not required



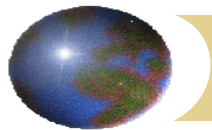
510(k) Classifies a New Device

- ✚ New device is classified by substantial equivalence (SE), or not equivalence (NSE)
- ✚ If SE then new device is same class as “predicate” device
- ✚ If NSE then it is Class III (it is also Class III until an SE decision)



510(k) Predicate

- ✚ Legally marketed device to which submitter claims equivalence
- ✚ Predicate does not have to be manufacturer's own device
- ✚ FDA guidance on selecting a predicate
- ✚ Also "reference" devices; technical aspect



Predicate Guidance

✚ Device advice on www.fda.gov

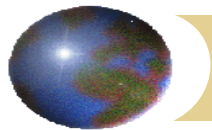
How To Find A Predicate Device

Introduction

Postamendments Device

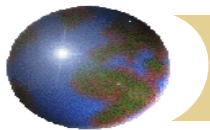
Preamendments Device

How to Search for a Predicate Device



510(k) Required When -

- ✚ Introducing a new device
- ✚ Making a significant change to a device:
labeling,
technology/engineering/performance,
materials
- ✚ FDA guidance on changes to devices



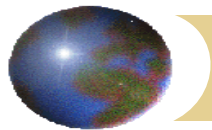
K97-1 Guidance

MEMORANDUM
510(k) Memorandum #K97-1

Date JAN 10 1997

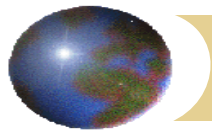
From Director, Office of Device Evaluation

Subject Deciding When to Submit a 510(k) for a Change to an Existing Device



Who Must Submit 510(k)

- ✚ Manufacturers
- ✚ Specification developers
- ✚ Repackagers who change device
- ✚ Relabelers who change intended use

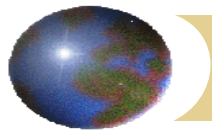


Who Does Not Submit 510(k)

✚ Private label distributor:

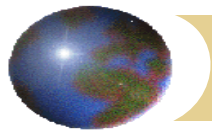
- ▣ "distributed by ..."
- ▣ "manufacturer for ..."

✚ Repackager who doesn't alter device or labeling



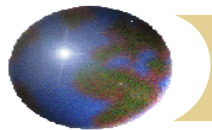
Different Types of 510(k)s

- ✚ Traditional 510(k) – addresses all content requirements and includes all necessary data
- ✚ Abbreviated 510(k) – relies on guidance, special controls, standards
- ✚ Special 510(k) – change to manufacturer's marketed device, summary of changes



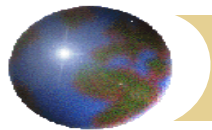
Traditional 510(k) Contents

- ✚ Administrative information
- ✚ Classification name, CFR number, class, "product code"
- ✚ Common and proprietary name/model
- ✚ Indications
- ✚ Truthful/accurate statement



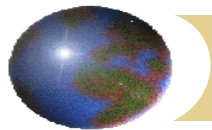
Traditional 510(k) Contents

- ✚ Labeling
- ✚ Standards statement
- ✚ Financial certification
- ✚ Predicates/reference device(s) and comparisons
- ✚ Data (preclinical, engineering, clinical)



Traditional 510(k) Contents

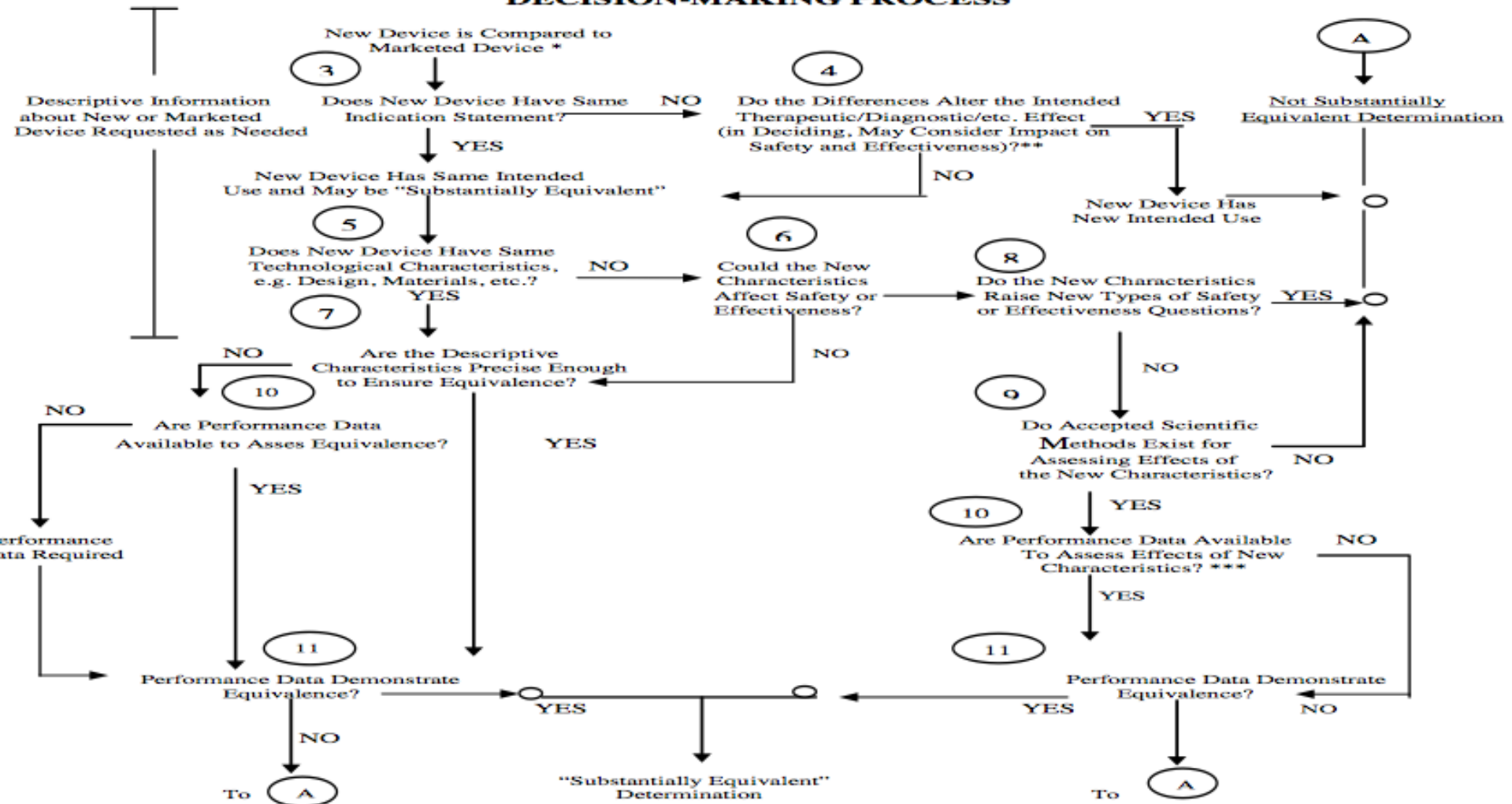
- ✚ 510(k) statement/summary
- ✚ Class III certification
- ✚ Sterilization information
- ✚ Software information
- ✚ ANY OTHER INFORMATION FDA REQUESTS

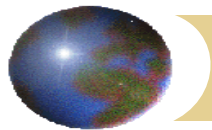


FDA SE Decision Algorithm

- ✚ FDA's has method to determine whether the new device is "substantially equivalent" to the claimed predicate device.
- ✚ Embedded in the law but elaborated by FDA in guidance. Decision flow chart completed by FDA but submitters often include in submission a suggested highlighted flow chart

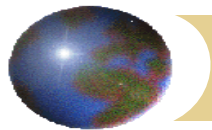
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS





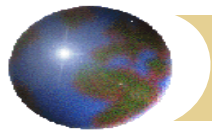
Abbreviated 510(k) Contents

- ✚ Submitter elects to submit summary reports on the use of guidance, special controls, and declarations of conformity to standards to expedite the review
- ✚ Describe in detail any deviations from the above documents and reasons.



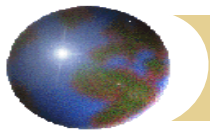
Special 510(k) Contents

- ✚ Contents in many respects are similar to a traditional 510(k) but the focus is on the specific change
- ✚ Include a “concise summary” of related design control activities and declaration of conformance to design controls: risk analysis, verification/validation test description



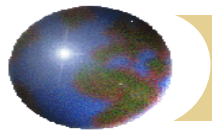
Review process

- ✚ 90 day review cycle
- ✚ Submission filing type review
- ✚ Usually one main FDA reviewer who can rely on any other inputs within FDA
- ✚ Reviewer may request additional information by letter, phone, or electronic means



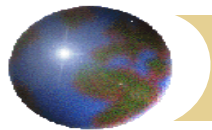
FDA Decisions on 510(k)

- ✚ Request for additional information
- ✚ Withdrawn for lack of response
- ✚ Not equivalent order
- ✚ Substantially equivalent order



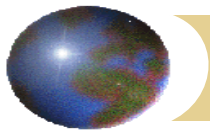
Submitter Action

- ✚ If SE then proceed to market
- ✚ If NSE then submit a PMA, a “De Novo”, correct the cause for NSE, if possible, or appeal (We won’t discuss De Novo)



510(k) Special Issues

- ✚ A firm may not BOTH manufacture and distribute a new device without their own 510(k)
- ✚ A device not in final form (unfinished), or in final form but not for sale does not need a 510(k)

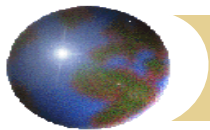


510(k) Guidance -Forms

510(k) Forms

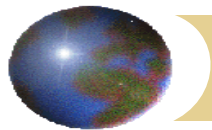
List of forms associated with Premarket Notification (510[k]) submissions

- **510(k) Pre-Review Form**
- **Exempt Device Review Form**
- **Acceptance Checklists for Traditional, Abbreviated, and Special 510(k)s**
- **510(k) Review Template**
- **510(k) Review Template Instructions**
- **510(k) Cover Sheet Memorandum**
- **510(k) “Substantial Equivalence” Decision Making Process**
- **Standards Data Form for Abbreviated 510(k)s**



510(k)Guidance - Forms

- Sterile Devices in Premarket Notification [510(k)] Submissions
- Description of 510(k) "Substantial Equivalence" Decision-Making Process (Accessible Text)
- Premarket Notification Class III Certification and Summary
- Premarket Notification Truthful And Accurate Statement
- Premarket Notification 510(k) Statement
- Required Elements for a Declaration of Conformity to a Recognized Standard
- 510(k) Indications For Use Form (PDF - 1.7MB)



510(k) Guidance

- ✚ Traditional, Abbreviated, Special 510(k) methods
- ✚ Changes to devices
- ✚ Predicates
- ✚ Product specific guidance
- ✚ Software guidance...